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10/533,726

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EXAMINER

LUCAS, ZACHARIAH

ART UNIT

PAPER NUMBER

1648

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|-------------------------------|-------------------------------|--|
| Office Action Summary | Application No. 10/533,726 | Applicant(s) KHANNA ET AL. | |
| | Examiner Zachariah Lucas | Art Unit 1648 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17,27-29,34,36-38 and 42-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-17,27-29,34,36-38 and 42-46 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Applicant is required to elect one of the following:

(a) an EBV epitope comprising the sequence of SEQ ID NO: 4 (claims 1, 12, 13, 27, 34, 36, and 42-46);

(b) an EBV epitope comprising the sequence of SEQ ID NO: 5 (claims 1, 12, 13, 27, 34, 36, and 42-46);

(c) an EBV epitope comprising the sequence of SEQ ID NO: 6 (claims 1, 12, 13, 27, 34, 36, and 42-46);

(d) an EBV epitope comprising the sequence of SEQ ID NO: 7 (claims 1, 12, 13, 27, 34, 36, and 42-46);

(e) an EBV epitope comprising the sequence of SEQ ID NO: 8 (claims 1, 12, 13, 27, 34, 36, and 42-46); or

(f) an EBV epitope comprising the sequence of SEQ ID NO: 3 (claim 11).

If (a) is elected, Applicant is required to elect one of SEQ ID NOs: 9-12 (each corresponding to claims 2 and 7-9 in addition to the claims corresponding to SEQ ID NO: 4); and if SEQ ID NO: 11 is elected, election is further required to one of SEQ ID NOs: 13 or 14 (each also found in claim 7).

If (b) is elected, Applicant is required to elect one of SEQ ID NOs: 16 (including SEQ ID NOs: 18 and 19, found in claim 7) or 17 (each of SEQ ID NOs: 16 and 17 corresponding to claims 3 and 7-9 in addition to the claims corresponding to SEQ ID NO: 5).

If (c) is elected, Applicant is required to elect one of SEQ ID NOs: 21-24 (where SEQ ID NO: 26 is included with subsequence SEQ ID NO: 23- each of 22-24 corresponding to claims 4 and 7-9 in addition to the claims corresponding to SEQ ID NO: 6; and claim 21 corresponding to claims 4, 7-11, 14-17, 28, 29, 37, and 38 in addition to the claims corresponding to SEQ ID NO: 6) or SEQ ID NO: 1 (corresponding to claims 9, 10, and 11); and

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if SEQ ID NO: 21 is elected, election is further required to one of SEQ ID NOs: 41-43 (claim 11); and

if SEQ ID NO: 1 is elected, election is further required to one of SEQ ID NOs: 49 or 50 (claim 11).

If (d) is elected, Applicant is required to elect one of SEQ ID NOs: 29-31 (each of 29 and 30 corresponding to claims 4 and 7-9 in addition to the claims corresponding to SEQ ID NO: 6; and with SEQ ID NO: 30 corresponding to claims 5, 7-11, 14-17, 28, 29, 37, and 38 in addition to the claims corresponding to SEQ ID NO: 6) or 34 (claim 7); and if either of SEQ ID NOs: 29 or 30 is elected, election is further required to one of SEQ ID NOs: 32, 33, or 35.

If (e) is elected, Applicant is required to elect one of SEQ ID NOs: 2 or 37 (each corresponding to claims 6 and 7-9 in addition to the claims corresponding to SEQ ID NO: 8).

If (f) is elected, Applicant is required to elect one of SEQ ID NOs: 44, 47, or 48 (each found in claim 11).

Further, Applicant is also required to elect one of the target diseases of claim 42 identified as:

- (i) a B-cell non-Hodgkin's lymphoma,
- (ii) a T-cell non-Hodgkin's lymphoma,,
- (ii) Hodgkin's lymphoma, or
- (ii) a lymphoepithelioma-like carcinoma (including NPC in claim 43).

Note- A linker sequence will be examined with an elected subsequence (except that a single linker sequence from SEQ ID NO: 32, 33, and 35 must be elected for either of SEQ ID NO: 29 or 30 as indicated above).

SEQ ID NO: 13 (claim 7) links SEQ ID NOs: 10 and 11.

SEQ ID NO: 14 (claim 7) links SEQ ID NO: 11 and 12.

SEQ ID NO: 15 (claim 7) links SEQ ID NO: 9-12, and encompasses SEQ ID NOs: 13 and 14.

SEQ ID NO: 20 (claim 7) links SEQ ID NOs: 16 and 17.

SEQ ID NO: 25 (claim 7) links SEQ ID NOs: 21, 22, and 24.

SEQ ID NO: 27 (claim 7) links SEQ ID NOs: 21-24, and encompasses SEQ ID NO: 25.

SEQ ID NO: 28 (claims 7-9) links SEQ ID NOs: 29 and 30.

SEQ ID NO: 32 (claim 7) links SEQ ID NOs: 29-31, and encompasses SEQ ID NO: 28.

SEQ ID NO: 33 (claim 7) links SEQ ID NOs: 29 and 30, and encompasses SEQ ID NO: 28.

SEQ ID NO: 35 (claim 7) links SEQ ID NOs: 29 and 30, and encompasses SEQ ID NO: 28.

SEQ ID NO: 36 (claim 7) links SEQ ID NOs: 29-31 and 34; and encompasses SEQ ID NOs: 28, 32, 33, and 35.

SEQ ID NO: 39 (claim 7) links SEQ ID NOs: 2 and 37.

SEQ ID NO: 81 (claims 17 and 29) links SEQ ID NOs: 21 and 30.

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Further, if SEQ ID NO: 30 is elected, the variant of SEQ ID NO: 40 will be examined therewith.

2. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

3. The claims are deemed to correspond to the species as indicated in the listing above.

The following claim(s) are generic: No claims are generic.

4. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: each of the species represents a distinct CTL epitope from EBV. EBV epitopes generally were known in the art. See e.g. WO 99/02550, claim 3 (reference of record in the May 2005 IDS). Thus, only common feature of the peptides (i.e. that they are EBV CTL epitopes) is not a special technical feature over the prior art. Similarly, the different diseases to be treated each share in common only that they are being treated by EBV peptides. Such is not a special technical feature over the art as shown by claim 20 of the WO reference. Unity is therefore lacking.

Conclusion

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

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application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Z. Lucas/
Patent Examiner, AU 1648